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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/267,963 03/12/99 MIYAZONO

K LUD-5539.1-C

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NEW YORK NY 10103-3198

EXAMINER

ROMEOLP
ART UNIT PAPER NUMBER

1647
DATE MAILED:

15
05/21/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/267,963

Applicant(s)
Miyazano et al.

Examiner
David Romeo

Art Unit
1647



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 Feb 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 14-20 and 28 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 14-20 and 28 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☒ Interview Summary (PTO-413) Paper No(s). 15
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: Notice to Comply; Raw Seq List Err Rep

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DETAILED ACTION

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 14-16, 18, 20, 28 to the extent that they are drawn to methods employing
5 an indeterminate inhibitor which inhibits the phosphorylation of Smad1 wherein
said inhibitor binds TGF- β and inhibits the binding of TGF- β and ALK-1, and
wherein said inhibitor inhibits the binding of Smad1 to ALK-1, indeterminate
classification.

II. Claims 14-16, 18, 20, 28 to the extent that they are drawn to methods employing
10 an indeterminate inhibitor which inhibits the phosphorylation of Smad5 wherein
said inhibitor binds TGF- β and inhibits the binding of TGF- β and ALK-1, and
wherein said inhibitor inhibits the binding of Smad5 to ALK-1, indeterminate
classification.

III. Claims 14, 15, 17, 18, 20, 28 to the extent that they are drawn to methods
15 employing an indeterminate inhibitor which inhibits the phosphorylation of Smad1,
wherein said inhibitor binds an extracellular domain of ALK-1 and inhibits the
binding of TGF- β and ALK-1, and wherein said inhibitor inhibits the binding of
Smad1 to ALK-1, indeterminate classification.

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- IV. Claims 14, 15, 17, 18, 20, 28 to the extent that they are drawn to methods employing an indeterminate inhibitor which inhibits the phosphorylation of Smad5 wherein said inhibitor binds an extracellular domain of ALK-1 and inhibits the binding of TGF- β and ALK-1, and wherein said inhibitor inhibits the binding of Smad5 to ALK-1, indeterminate classification.
- V. Claims 14, 18, 19 to the extent that they are drawn to methods employing an inhibitor which inhibits the phosphorylation of Smad1, wherein said inhibitor inhibits the binding of Smad1 to ALK-1, and wherein said inhibitor is Smad6, classified in class 435, subclass 7.8.
- VI. Claims 14, 18, 19 to the extent that they are drawn to methods employing an inhibitor which inhibits the phosphorylation of Smad5, wherein said inhibitor inhibits the binding of Smad5 to ALK-1, and wherein said inhibitor is Smad6, classified in class 435, subclass 7.8.
- VII. Claims 14, 18, 19 to the extent that they are drawn to methods employing an inhibitor which inhibits the phosphorylation of Smad1, wherein said inhibitor inhibits the binding of Smad1 to ALK-1, and wherein said inhibitor is Smad7, classified in class 435, subclass 7.8.
- VIII. Claims 14, 18, 19 to the extent that they are drawn to methods employing an inhibitor which inhibits the phosphorylation of Smad5, wherein said inhibitor

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inhibits the binding of Smad5 to ALK-1, and wherein said inhibitor is Smad7,
classified in class 435, subclass 7.8.

2. The inventions are distinct, each from the other because of the following reasons:

5 The following pairwise combinations of methods are independent and distinct, wherein
each member of a pair performs different functions, using different starting materials and/or
process steps and/or with different outcomes: I and each of II-VIII; II and each of III-VIII; III
and each of IV-VIII; IV and each of V-VIII; V and each of VI-VIII; VI and each of VI-VIII; VII
and each of VIII.

10 3. Because these inventions are distinct for the reasons given above and have acquired a
separate status in the art as shown by their different or indeterminate classification, restriction for
examination purposes as indicated is proper.

4. Because these inventions are distinct for the reasons given above and the searches required
are not coextensive, restriction for examination purposes as indicated is proper.

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5. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

6. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

7. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

8. Newly submitted claim 28 is directed to an invention that is independent or distinct from the invention originally claimed for the following reasons: Newly submitted claim 28 is directed to the activation of ALK-1. The invention originally claimed is presumably directed to the inhibition of Smad1 or Smad5 phosphorylation.

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Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claim 28 is withdrawn from consideration to the extent that it is directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

5

Formal Matters

9. The communication filed 03/08/2001 is not fully responsive to the Office communication mailed 08/15/2000 (Paper No. 9) for the reason(s) set forth on the attached Notice To Comply With The Sequence Rules and Raw Sequence Listing Error Report. The above-mentioned reply appears to be *bona fide* attempt to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825).

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10. Applicants' arguments in the response filed 02/14/2001 (Paper No. 11) will be considered in the next Office action.

11. In a telephone interview with Mary Anne Schofield on May 14, 2001 a proposed examiner's amendment was discussed. Upon further consideration the proposed examiner's amendment is withdrawn.

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ANY INQUIRY CONCERNING THIS COMMUNICATION OR EARLIER COMMUNICATIONS FROM THE EXAMINER SHOULD BE DIRECTED TO DAVID S. ROMEO WHOSE TELEPHONE NUMBER IS (703) 305-4050. THE EXAMINER CAN NORMALLY BE REACHED ON MONDAY THROUGH FRIDAY FROM 6:45 A.M. TO 3:15 P.M.

5 IF ATTEMPTS TO REACH THE EXAMINER BY TELEPHONE ARE UNSUCCESSFUL, THE EXAMINER'S SUPERVISOR, GARY KUNZ, CAN BE REACHED ON (703) 308-4623.

OFFICIAL PAPERS FILED BY FAX SHOULD BE DIRECTED TO (703) 308-4242.

FAXED DRAFT OR INFORMAL COMMUNICATIONS SHOULD BE DIRECTED TO THE EXAMINER AT (703) 308-0294.

ANY INQUIRY OF A GENERAL NATURE OR RELATING TO THE STATUS OF THIS APPLICATION OR PROCEEDING SHOULD BE DIRECTED TO THE GROUP RECEPTIONIST WHOSE TELEPHONE NUMBER IS (703) 308-0196.

10 
DAVID ROMEO
PRIMARY EXAMINER
ART UNIT 1647

MAY 19, 2001

NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE DISCLOSURES

The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):

- ☒ 1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).
- ☐ 2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).
- ☐ 3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).
- ☒ 4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."
- ☐ 5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).
- ☐ 6. The paper copy of the "Sequence Listing" is not the same as the computer readable form of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).
- ☐ 7. Other: _____

Applicant Must Provide:

- ☒ ~~An initial or~~ substitute computer readable form (CRF) copy of the "Sequence Listing".
- ☐ An initial or substitute paper copy of the "Sequence Listing", as well as an amendment directing its entry into the specification.
- ☒ A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).

For questions regarding compliance to these requirements, please contact:

For Rules Interpretation, call (703) 308-4216

For CRF Submission Help, call (703) 308-4212

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